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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,670	07/23/2001	Andrew W. Taylor	ERI-114AX	6394

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/912,670	TAYLOR ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2005 and 28 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,42 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,42 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 5/11/05 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment and remarks, filed 5/11/05, and additional remarks and 1.132 declaration of Inventor Taylor, filed 7/28/05, have been entered.

In view of Applicant's remarks, now citing support for the previously added claims, the previous rejections under 35 U.S.C. § 112, first paragraph have been withdrawn.

2. Claim 24, 42, and 43 are pending and being acted upon.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 24 and 42 stands rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,048,850 in view of Lipton et al. (1997, IDS) for the reasons of record.

As set forth previously, The '850 patent teaches a method for down-regulating a T cell-mediated autoimmune response (arthritis) in a tissue site in an animal, comprising directly injecting genetic material for an anti-inflammatory compound, into or near the autoimmune-diseased tissue site (see particularly column 30, lines 48-64).

The reference teaching differs from the claimed invention only in that it does not teach the use of α-MSH as the anti-inflammatory compound.

Lipton et al. teaches the use of α-MSH as an anti-inflammatory compound for the down-regulation of a T cell-mediated autoimmune response (see particularly page 141, column 2, Box I).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method for down-regulating a T

cell-mediated autoimmune response (arthritis) in a tissue site in an animal, comprising directly injecting genetic material for an anti-inflammatory compound, into or near the autoimmune-diseased tissue site, as taught by the '850 patent, employing α-MSH as the anti-inflammatory compound, as taught by Lipton et al. One of ordinary skill in the art at the time the invention was made would have been motivated to employ α-MSH as the anti-inflammatory compound of the invention because α-MSH was a well-known anti-inflammatory compound at the time of the invention. It is well-established that the substituting of equivalents, in this instance one anti-inflammatory for another, for the same purpose is obvious, see MPEP 2144.06.

Applicant's arguments, filed 5/11/05, have been fully considered but they are not persuasive. Applicant argues that Lipton adds nothing to the disclosure of the '850 patent which generally teaches gene therapy for treating inflammation.

It remains the Examiners position that the substitution of the anti-inflammatory αMSH agent of Lipton et al. into the method of the '850 patent, i.e., the method of the instant claims, would have been obvious to the ordinarily skilled artisan.

Applicant's arguments, filed 7/28/05, have been fully considered but they are not persuasive. Applicant argues a lack of motivation to combine the references without impermissible hindsight. Specifically, Applicant argues that there is no direction in the primary reference to look to the teachings of Lipton et al. Applicant summarizes selected sections of both references.

Regarding the use of hindsight, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant is advised that the references are not viewed in a vacuum. The ordinarily skilled artisan is aware of the work of other artisans in the field. In the instant case, the ordinarily skilled artisan, in viewing the method of the '850 patent, would have been aware of the anti-inflammatory αMSH agent of Lipton et al.; its substitution for the anti-inflammatory agent in the method would then have been obvious.

5. Claim 43 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,048,850 in view of Lipton et al. (1997, IDS), as applied to Claims 24 and 42 above, and in further view of Singh et al. (1996).

As set forth previously, U.S. Patent No. 6,048,850 and Lipton et al. have been discussed above. The references differ from the claimed invention in that they do not teach the use of α-MSH for the treatment of a disease wherein the autoimmune-diseased tissue site is an eye of an animal.

Singh et al. teaches that uveitis is a T cell-mediated disease that is the major cause of visual impairment in humans (see particularly the Abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform the method of the '850 patent, employing α-MSH as the anti-inflammatory compound, as taught by Lipton et al., for the treatment of autoimmune-diseased tissue of the eye of an animal. One of ordinary skill in the art at the time the invention was made would have been motivated to treat uveitis (a T cell-mediated autoimmune disease of the eye tissue) given the teachings of Singh et al. that uveitis is the major cause of visual impairment in humans; accordingly, effective treatments would be desirable.

Applicant has not traversed this rejection separately. See section 4 above.

6. Applicant has submitted a 1.132 declaration of Inventor Taylor. The declaration indicates that αMSH is a more effective anti-inflammatory agent when αMSH DNA is administered locally than when administered systemically. The Declarant's findings are noted, however, it is unclear how they effect the prosecution of the instant application.

7. The following are new grounds for rejection.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 24, 42, and 43 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at

the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) The method of claim 24, wherein a T^1 cell-mediated response in downregulated in an affected tissue site wherein αMSH genetic material is administered locally.

Applicant fails to indicate that no new matter had been added, no support has been identified in the specification for the amendment, and none has been found.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

12. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see www.uspto.gov/ebc/newusers.html. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/GE/
8/3/05

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Primary Examiner
Technology Center 1600